cell disorders, such as iron deficiency anemia.

(b) *Classification.* Class II (performance standards).

### § 866.5890 Inter-*alpha* trypsin inhibitor immunological test system.

(a) *Identification.* An inter-*alpha* trypsin inhibitor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the inter-*alpha* trypsin inhibitor (a protein) in serum and other body fluids. Measurement of inter-*alpha* trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 53 FR 11253, Apr. 6, 1988; 65 FR 2313, Jan. 14, 2000]

## Subpart G—Tumor Associated Antigen immunological Test Systems

### § 866.6010 Tumor-associated antigen immunological test system.

(a) *Identification.* A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.

(b) *Classification.* Class II (special controls). Tumor markers must comply with the following special controls: (1) A guidance document entitled ''Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications (510(k)s) to FDA,'' and (2) voluntary assay performance standards issued by the National Committee on Clinical Laboratory Standards.

[62 FR 66005, Dec. 17, 1997]

### § 866.6020 Immunomagnetic circulating cancer cell selection and enumeration system.

(a) *Identification.* An immunomagnetic circulating cancer cell selection and enumeration system is a device that consists of biological probes, fluorochromes, and other reagents; preservation and preparation devices; and a semiautomated analytical instrument to select and count circulating cancer cells in a prepared sample of whole blood. This device is intended for adjunctive use in monitoring or predicting cancer disease progression, response to therapy, and for the detection of recurrent disease.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System.'' See § 866.1(e) for availability of this guidance document.

[69 FR 26038, May 11, 2004]

# PART 868—ANESTHESIOLOGY DEVICES

## Subpart A—General Provisions



## Subpart B—Diagnostic Devices